IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT :

THE HONOURABLE MR. JUSTICE K.A.ABDUL GAFOOR

WEDNESDAY, THE 13TH DECEMBER 2006 / 22ND AGRAHAYANA1928

OP.No. 14979 of 2001(G)

PETITIONER:

GERNAN REMEDIES LTD., A COMPANY
REGISTERED UNDER THE PROVISIONS
OF THE INDIAN COMPANIES ACT 1913,
HAVING REGISTERE ADDRESS AT
SHIVSAGAR ESTATE, 'A' BLOCK,
DR. ANNIE BESANT RD.,
WORLI, MUMBAI - 400 018.

BY ADV. SRI.B.S.KRISHNAN (SR.)
SMT.LATHA KRISHNAN

RESPONDENTS:

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1. STATE OF KERALA, REPRESENTED BY
THE CHIEF SECRETARY TO GOVT.,
SECRETARIAT, THIRUVANANTHAPURAM.

2. THE DRUGS CONTROLLER GENERAL OF INDIA,
NEW DELHI.

3. DRUGS INSPECTOR (ADDITIONAL),
PATHANMATHITTA.

BY GOVERNMENT PLEADER SRI.BENNY GERVACIS
SRI JOHN VARGHESE ASG
SRI.M.K.SUCHEENDRAN, ADDL.CGSC

THIS ORIGINAL PETITION HAVING BEEN FINALLY HEARD ON 13/12/2006, THE COURT ON THE SAME DAY DELIVERED THE FOLLOWING:

ORDER ON C.M.P..NO.23552/01 IN O.P.NO.14979/01

DISMISSED.

Sd/-
(K.A.ABDUL GAFOOR)
13.12.2006. JUDGE

APPENDIX

PETITIONERS' EXHIBITS:

EXT.P1: TRUE COPY OF THE NOVARTIS LETTER DT. 11.12.98 SEEKING CLARIFICATION TO JT.COMMISSIONER AFOOD AND DRUGS ADM, MAHARASHTRA.

EXT.P2: TRUE COPY OF LETTER DT. 20.11-98 FROM DRUGS CONTROLLER, ORISSA.

EXT.P3: TRUE COPY OF RELEVANT PORTION OF INDIAN PHARMACOPOEIA, 1985.

EXT.P4: TRUE COPY OF THE RELEVANT PORTION OF INDIAN PHARMACOPOEIA, 1996.

EXT.P5: TRUE COPY OF LETTER DT. 22.2.99 FROM FOOD & DRUGS ADM, MAHARASHTRA.

EXT.P5(a): TRUE COPY OF THE ENGLISH TRANSLATION OF Ext.P5.

EXT.P6 TRUE COPY OF LETTER DT. 28.7.99 FROM DRUGS CONTROLLER, THIRUVANANTHAPURAM.

EXT.P7 TRUE COPY OF COMPLAINT BEFORE CHIEF JUDICIAL MAGISTRATE, PATHANAMTHITTA.

EXT.P8 TRUE COPY OF NOTIFICATION DT. 22.9.99 FROM DRUGS CONTROLLER OF INDIA, DELHI.

EXT.P9 TRUE COPY OF THE ORIGIN AND OBJECT OF THE INDIAN PHARMACOPOEIA.

EXT.P10 TRUE COPY OF THE RELEVANT PORTION OF THE RELEVANT PORTION OF THE INDIAN PHARMACOPOEIA PRIOR TO AMENDMENT IN 1996.

EXT.P11 TRUE COPY OF THE RELEVANT PORTION OF THE RELEVANT PORTION OF THE AMENDED INDIAN PHARMACOPOEIA OF 1996.

EXT.P12 TRUE COPY OF THE LETTER ADDRESSED TO THE JOINT COMMISSIONER FOOD AND DRUGS, MUMBAI.

RESPONDENTS' EXHIBITS: NIL

sk/-

//true copy//

P.S. To Judge.

K.A.ABDUL GAFOOR, J.

O.P.No.14979 of 2001

Dated this the 13th day of December, 2006.

JUDGMENT

Abdul Gafoor, J.

The petitioner is a drug manufacturer. In relation to the drug manufactured by the petitioner viz. Syntocinon, which contains Oxytocin, the Drug Inspector detected that labelling was not in conformity with Rule 96(vii) of the Drugs and Cosmetics Rules, 1945 and entry No.8 under the heading 'Miscellaneous Drugs' in Schedule P to the said Rules. Accordingly, prosecution was initiated alleging violation of the relevant provisions, lodging Ext.P7 F.I.R. This is sought to be quashed in this writ petition.

2. It is submitted that the said medicine is included as item No.8 under the heading 'Miscellaneous Drugs' in Schedule P to the Rules whereby the storage condition is mentioned as "cold place", which is further described in the foot note of

the said schedule as "at a temperature between 2 degree centigrade and 8 degree centigrade" which shall be available in Kerala, only inside a 'refrigerator' other than a 'freezer'. But the labelling contained in the item of medicine manufactured by the petitioner indicated the storage condition as "store in a cool place and should not be allowed to freeze".

3. 'Cool place', according to the schedule to the Rules, is a place where the temperature is between 10 degree and 25 degree. This was adopted, according to the petitioner, because of the storage conditions in the Indian Pharmacopocia, 1996, Ext.P10 as amended by Ext.P4. It is also submitted that, a learned single Judge has considered this aspect in respect of the very same medicine manufactured by another manufacturer and

had found that because of this confusion arising because of the condition contained in the Rules and the description in Indian Pharmacopocia, 1996, the prosecution ought not to have been launched. Thus, it is submitted that the said view shall be adopted in this case. Therefore, Ext.P7 shall be quashed.

3. It is submitted by the Government Pleader, justifying the launching of the prosecution as per Ext.P7, that the medicine in question is one mentioned under the heading 'miscellaneous drugs' in Schedule P covered by Rule 96(vii) of the Rules. Necessarily, the manufacturer has, with reference to the labelling, to conform to the standards mentioned in Schedule P in relation to the said drug. If the labelling of the medicine will affect its potency. This is an important medicine to be administered at the time of child birth. The administration of the drug,

the potency of which has been reduced because of the change in the storage condition, may turn fatal and therefore, the prosecution shall be allowed to continue the proceedings.

4. It is submitted that the Indian Pharmacopocia is having statutory recognition as mentioned in the rules. Therefore, the specifications in Inidan Pharmacopocia, is also to be followed. The specification regarding the storage of the medicine concerned mentioned in the India Pharmacopocia, as amended by Ext.P4 is, 'store in cool place and should not be allowed to freeze'. This will necessarily mean that the said 'cool place' is a place where there is a chance of freezing. Therefore, it cannot be room temperature. When this phraseology is used in India Pharmacopocia, it is not opposed to the storage conditions mentioned in Schedule P. So, it cannot be

stated that there was commission of any offence to launch the prosecution.

5. Anyhow, by now, the petitioner is following strictly the storage conditions mentioned in Schedule P for the purpose of labelling the drug in question. Another single Judge has already taken a view that it was because of the confusion regarding the storage place as mentioned in Schedule P and the India Pharmacopocia, this situation had arisen. In such circumstances, following the said view, which has not been appealed against with respect to that aspect, Ext.P7 is quashed.

Writ petition is allowed as above.

Sd/-
(K.A.ABDUL GAFOOR)
JUDGE

sk/

//true copy//

K.A.ABDUL GAFOOR, J.

O.P.No.14979 of 2001

JUDGMENT

13th December, 2006.